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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,019	10/28/2003	Arthur Rick Alleman	UF-387	7481

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,019	ALLEMAN ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 37-43* is/are pending in the application.

4a) Of the above claim(s) *8-17 and 37* is/are withdrawn from consideration.

5)☒ Claim(s) *1-7 and 38-43* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed April 25, 2007 has been received and entered. Claims 18-36 & 44 have been canceled. Accordingly, claims 1-17 and 37-37-43 are pending in the instant application, of which claims 8-17, and 37 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

1. The objection of claims 1-7 and 38-44 for reciting "as set forth in Table 2" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-7 and 39-44 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the Patent Office's reliance on Lilly and Fiers in support of its position that the claimed inventions fails the written description requirement with respect to fragments of SEQ ID NO: 3 is misplaced. In cases such as Lilly and Fiers, the patent specifications at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. Applicants respectfully point out that Table 2 provides actual written description of various polypeptide fragments of SEQ

ID NO: 3. Applicants further assert that the term "comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the Patent Office's reliance on Lilly and Fiers in support of its position that the claimed inventions fails the written description requirement with respect to fragments of SEQ ID NO: 3 is misplaced, that cases such as Lilly and Fiers, the patent specifications at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. However, Applicants claimed genus, any protein having a minimum of 16 consecutive amino acids in common with SEQ ID NO: 3, is supported by a single solitary species, SEQ ID NO: 3 of the instant invention. The Lilly court set out exemplary ways in which a genus of cDNAs could be described: A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This issue was revisited in *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court held that "the written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when

coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See id. At 1324, 63 USPQ2d at 1613.

With respect to the use of an assay to support written description, in *University of Rochester v G. D. Searle & Co. Inc.,* 358 F.3d 916, 925, 69 USPQ2d 1886, 893 (Fed Cir. 2004), the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (COX-2) by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human." The patent described in detail how to make cells that express either COX-1 or COX-2, but not both, as well as assays for screening compounds, including peptides, polynulceotides and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product. Id at 927, 69 USPQ2d at 1895.

The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides have the desired characteristic, the claims failed to meet the description requirement of 35 USC 112. The instant application is directly analogous in that Applicants specification provides no description of any "fragment" which was able to induce a protective immune response in an animal or human.

To further address this point, the following references are cited:

Plotkin et al (VACCINES W.B. Saunders Company, 1988, page 571) "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen."

Briles et al (US Patent Number 5,955,089) set forth that "B cell epitopes are often not linear amino acid sequences but rather result from the tertiary structure of the folded three dimensional protein." (See summary). Given that 16 consecutive amino acids will exhibit minimal folding, one of skill in the art would be forced into excessive experimentation to figure out a three dimensional epitope using short linear peptides.

Furthermore, Applicants specification provides no working examples demonstrating prevention with the polypeptide (SEQ ID NO: 3) of the instant invention or any fragment thereof.

Protective immunity "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Accordingly, the limited fragment structure disclosed by Applicants does not display a functional characteristic (protective immunity) which can be correlated.

Finally, Applicants assert that the term "comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. Applicants arguments are correct. However, the standard for fulfilling the written description requirement remains the same. Applicants have disclosed a single solitary species (SEQ ID NO: 3), not a representative number of species to satisfy the written description requirement for a genus of proteins sharing at a minimum 16 consecutive amino acids. As a suggestion, amendment of the claims to recite "consisting of at least 16 consecutive amino acids of SEQ ID NO: 3 fused to a heterologous sequence" and limiting to

"eliciting an immune response" would be sufficient to overcome the written description rejection.

Claims 1-7 and 39-44 recite polypeptide fragments ***comprising*** between 16 and 88 contiguous amino acids of SEQ ID NO: 3, as well as other non full length peptides. (Emphasis added).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a "fragment sharing 16 contiguous amino acids with SEQ ID NO: 3" alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." (Emphasis added).

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 1-7, 39 and 44 under 35 U.S.C. 102(b) as being anticipated by Knowles et al is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-7, 39, and 42-44 under 35 U.S.C. 103(a) as being unpatentable over Knowles et al in view of Vaughan et al is withdrawn in view of Applicants amendment.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Navarro
Primary Examiner
May 23, 2007